

Attachment A

Westlaw.

2003 WL 21279863 (Bd.Pat.App & Interf.)
(Cite as: 2003 WL 21279863 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)

EX PARTE JEFFREY L. HAVENS, DONALD P. SMITH, MICHAEL S. BERGREN AND MARK A.
LYSTER

Appeal No. 2001-0091

Application No. 08/732,254

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

BRUCE STEIN

PHARMACIA & UPJOHN COMPANY

INTELLECTUAL PROPERTY LEGAL SERVICES

301 HENRIETTA STREET

KALAMAZOO, MI 49001

Before WINTERS, ROBINSON, and GRIMES

Administrative Patent Judges

GRIMES

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

An oral hearing in this case was scheduled for November 27, 2001. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record.

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 2. Claims 1 and 2 are directed to specific crystal forms (form "S" and form "T," respectively) of 1-[5- Methanesulfonamidindolyl-2-carbonyl]-4-[3-(1-methylethylamino)-2-pyridinyl]-piperazine. monomethanesulfonate salt. [FN1] The claims list the powder X-ray diffraction measurements that distinguish the claimed crystal forms from other forms of delavirdine mesylate.

The examiner relies on the following reference:

Palmer et al. (Palmer) 5,563,142 Oct. 8, 1996

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(e) as anticipated by Palmer.

Claims 1 and 2 also stand rejected under 35 U.S.C. § 103 as obvious over Palmer.

Claims 1 and 2 also stand rejected for both statutory and obviousness-type double patenting, based on the claims of Palmer.

We reverse all of the rejections.

Discussion

The claims are directed to delavirdine mesylate in the S crystal form (claim 1) or in the T crystal form (claim 2). The examiner rejected the claims, under several different rationales, over the Palmer patent.

1. Statutory double patenting

The examiner rejected the claims under 35 U.S.C. § 101 "as claiming the same invention as that of claim 11 of prior U.S. Patent No. 5563142." Examiner's Answer, page 4. The examiner explained that "[i]n the absence of evidence showing otherwise, either of the instant claims may be the same compound recited in US'142." Id.

"35 U.S.C. § 101 prevents two patents from issuing on the same invention.... A good test, and probably the only objective test, for 'same invention,' is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention.... If it is determined that the same invention is being claimed twice, 35 U.S.C. § 101 forbids the grant of the second patent." In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 621-22 (CCPA 1970).

*2 Here, the patent's claim 11 is directed to delavirdine mesylate, without limitation as to crystal form. Instant claims 1 and 2 are directed to delavirdine mesylate in the S and T crystal forms, respectively. Thus, delavirdine mesylate in any crystal form other than S or T, or in a noncrystalline form, would infringe Palmer's claim 11 without infringing either of the claims on appeal. Therefore, the claims on appeal are not directed to the "same invention" as Palmer's claim 11 and are not unpatentable on that basis. The rejection under 35 U.S.C. § 101 is reversed.

2. Anticipation

The examiner rejected the claims under 35 U.S.C. § 102(e) on the basis that "Palmer discloses by name the same chemical compound as the mono methanesulfonate salt. See claim 11 in the US patent. In view of this fact evidence is needed that the prior art compound inherently lacks the characteristics (**x-ray diffraction spectra** recited in claims 1 and 2) relied on herein." Examiner's Answer, page 3.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "An inherent structure, composition or function is not necessarily known.... Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation." Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

"'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirk v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)). When the inherent properties of a prior art product are at issue, "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency. Ex parte Skinner, 2 USPQ2d 1788, 1789 (Bd. Pat. App. Int. 1986).

Here, the claims on appeal are not directed to delavirdine mesylate per se, but are limited to the S and T crystal forms of that compound. Therefore, to anticipate the claims, the prior art must disclose delavirdine mesylate in the S and T crystal forms. The examiner has provided no evidence or scientific reasoning to show that the delavirdine mesylate disclosed and claimed by Palmer is in either the S or T crystal form. Therefore, the examiner has not made out a prima facie case of anticipation by inherency.

*3 The examiner's attempt to shift the burden of proof to Appellants was premature. The burden shifts to the applicant only if the examiner can show, by evidence or scientific reasoning, a reasonable basis for concluding that the prior art product meets all the limitations of the claims. The examiner has provided no basis for such a conclusion in this case. The rejection under 35 U.S.C. § 102 is reversed.

3. Obviousness

The examiner rejected the claims under 35 U.S.C. § 103 on the basis that Palmer "discloses the free form of the instant sulfonate salts for use in treating HIV." Examiner's Answer, page 3. The examiner concluded that the corresponding methanesulfonate salt would have been an obvious variant because Palmer "teaches and in fact prefers the use of salt forms for better solubility and crystallinity," and methanesulfonate salts were exemplified for compounds other than delavirdine mesylate. Id., pages 3-4.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

The examiner's obviousness rejection seems to suffer the same infirmity as her anticipation rejection, namely, that it is directed to delavirdine mesylate per se, rather than to the specific S and T crystal forms of delavirdine mesylate that are the subject of the claims on appeal. The examiner has provided no evidence or convincing reasoning why the prior art disclosure of delavirdine mesylate in an undefined state would have suggested the specific S and T crystal forms that are the subject of the instant claims.

Nor has the examiner established that Palmer would have enabled those skilled in the art to make the claimed S and T crystal forms of delavirdine mesylate. Appellants' specification discloses specific conditions for recrystallizing delavirdine mesylate that produce the S and T crystal forms. See pages 2-4 and Examples 1-8. Palmer does not disclose or suggest even the existence of the S and T crystal forms of delavirdine mesylate, let alone how to make them. As stated in In re Hoeksema:

[I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. *4 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968) (footnote omitted).

Since the examiner has not established that Palmer would have rendered the claimed invention obvious to those skilled in the art, she has not made out a prima facie case under 35 U.S.C. § 103. The rejection for obviousness is reversed.

4. Obviousness-type double patenting

The examiner rejected the claims for obviousness-type double patenting over Palmer's claim 11. The examiner argues that the instant claims and Palmer's claim 11 are not patentably distinct because they contain "overlapping subject matter" and because Palmer also claims the free form of delavirdine, which is an obvious variant of delavirdine mesylate. Examiner's Answer, page 4.

Obviousness-type double patenting ... requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later.
In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998) (citation omitted, emphasis added).

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All proper double patenting rejections, of either type, rest on the fact that a patent has been issued and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent, of the very same invention claimed therein (same invention type double patenting) or of a mere variation of that invention which would have been obvious to those of ordinary skill in the relevant art (obviousness-type double patenting). In the latter case, there must be some clear evidence to establish why the variation would have been obvious. In re Kaplan, 789 F.2d 1574, 1579-80, 229 USPQ 678, 683 (Fed. Cir. 1986) (emphasis in original).

Thus, a proper rejection for obviousness-type double patenting requires showing that the later-claimed subject matter "would have been obvious to those of ordinary skill in the relevant art" based on the claims in the earlier patent. As discussed above, the examiner has pointed to nothing in either the claims or the disclosure of the Palmer patent that would have suggested the S and T crystal forms of delavirdine mesylate to a person of ordinary skill in the art. We therefore reverse the rejection for obviousness-type double patenting.

Summary

We reverse all of the rejections because the examiner has not established that the prior art disclosed or suggested the claimed S and T crystal forms of delavirdine mesylate.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

*5 SHERMAN D. WINTERS.

Administrative Patent Judge

DOUGLAS W. ROBINSON

Administrative Patent Judge

ERIC GRIMES

Administrative Patent Judge

FN1. This compound is also known as delavirdine mesylate, Appeal Brief, page 2, and we will refer to it as such.

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